

In the United States Court of Federal Claims

No. 11-223C

(Filed: April 12, 2016)¹

AMERICAN INNOTEK, INC.,

Plaintiff,

v.

THE UNITED STATES,

Defendant.

Patent Infringement; 28 U.S.C. §
1498; Claim Construction; Claim
Differentiation; Prosecution
History Disclaimer; Indefiniteness;
35 U.S.C. § 112.

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Of Counsel, for Defendant.

SECOND CLAIM CONSTRUCTION OPINION AND ORDER

WILLIAMS, Judge.

This patent infringement case involves bags for the containment and disposal of bodily fluids. Plaintiff, American Innotek, Inc. (“American Innotek”), claims that the United States infringed United States Patent No. 5,116,139 entitled “Fluid Containment Bag” (the “139 Patent”) by purchasing and using the accused product, a containment bag called the “Piddle Pak with Powder.” The accused product was manufactured by New York City Industries for the Blind

¹ The Court issued this Opinion under seal on March 31, 2016, and directed the parties to file proposed redactions by April 12, 2016. Neither party proposed redactions. The Court has not corrected grammatical errors in quotations from the exhibits. Accordingly, the Court publishes this Opinion correcting errata.

(“NYCIB”), a non-profit entity that provides products to the Government on a noncompetitive basis pursuant to the Javits Wagner O’Day Act (“JWOD”).²

In 2001, a government entity, the JWOD Committee for Purchase from People Who are Blind or Severely Disabled (“Committee”) placed the accused product, NYCIB’s Piddle Pak with Powder, on the JWOD procurement list as a mandatory source item for government agencies. Plaintiff alleges that as a result of this listing and the ensuing mandatory purchases and use by government agencies, its patent was infringed. Plaintiff contends that it lost government sales of its competing product, the *Flight Extender*, a urine containment bag using hydrophilic material, and seeks to recoup damages for the period of April 8, 2005 to May 26, 2009. PX 36 at A88-89.

The Court issued its first claim construction opinion on May 24, 2013, American Innotek, Inc. v. United States, 113 Fed. Cl. 668 (2013), and held a trial on liability and damages from September 16 through September 18, 2014, and September 30 through October 3, 2014. In the briefing following trial, the parties disputed the construction of an additional term that was not previously addressed. On October 6, 2015, the Court held oral argument to further develop the record on claim construction. Following argument, the parties submitted supplemental briefing addressing claim construction, concluding on December 28, 2015.

Findings of Fact³

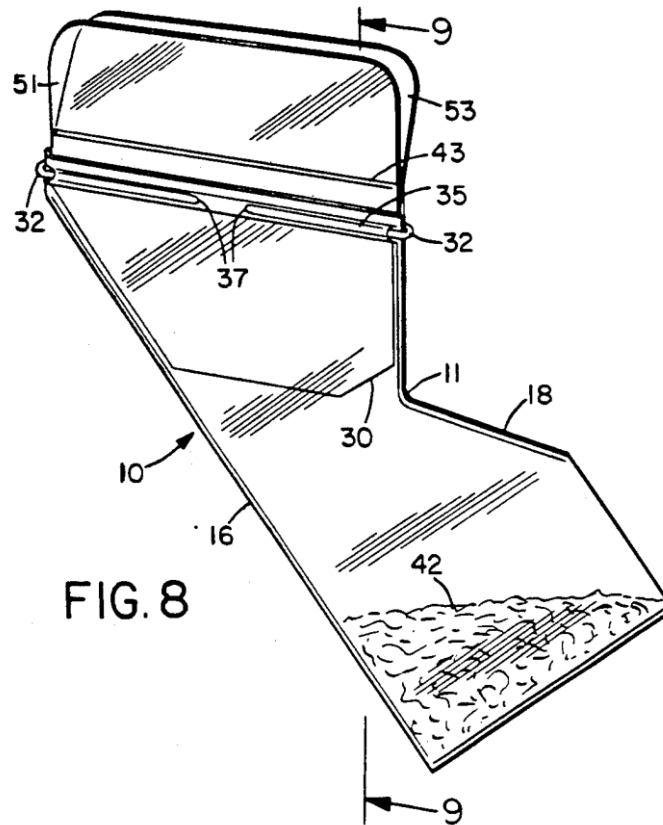
The ’139 Patent

The United States Patent and Trademark Office (“PTO”) issued the ’139 Patent entitled “Fluid Containment Bag” on May 26, 1992, from U.S. Patent Application No. 657,354 (the “’354 Application”), filed on February 15, 1991. JX 178. The ’139 Patent lists four inventors: Ruth E. Young, Daniel L. Young, Richard E. Warrick, and Clarence A. Cassidy, and is assigned to American Innotek, Inc. Id. The ’354 Application is a continuation-in-part of application No. 404,734 (the “’734 Application”), filed September 8, 1989, which itself is a continuation-in-part of application No. 3,848 (the “’848 Application”), filed January 14, 1987. Id. Both the ’734 and ’848 Applications were abandoned. Id. The ’139 Patent expired on May 26, 2009. DX 154 ¶ 6.

² Javits Wagner O’Day Act, Pub. L. No. 92-28, § 1, 85 Stat. 77 (1971) (codified as amended at 41 U.S.C. §§ 46-48c (2006)) (“JWOD”). JWOD was further amended in 2011, and codified at 41 U.S.C. §§ 8501-06, effective January 4, 2011. The Court relies on the 2006 version of the Code here, the version in effect at the time of conduct at issue.

³ These findings of fact are derived from the record developed at trial. Unless otherwise noted, “Tr.” references the trial transcript, PX references Plaintiff’s exhibits, DX references Defendant’s exhibits, and JX references the parties’ joint exhibits. Additional findings of fact are in the Discussion and the Court’s prior claim construction opinion, American Innotek, Inc. v. United States, 113 Fed. Cl. 668, 671-74 (2013).

The '139 Patent teaches a "containment and disposal bag for human bodily fluids." '139 Patent Abstract. The specification provides the following drawing as representative of the '139 Patent:



'139 Patent Fig. 8.

The '139 Patent contains one independent claim and 16 dependent claims. '139 Patent 8:39 – 10:30. American Innotek asserts that the NYCIB's Piddle Pak with Powder infringes independent Claim 1, and dependent Claims 2-4 and 17.

Independent Claim 1 discloses:

1. A containment bag for a fluid comprising water or water-based liquid such as bodily fluids which comprises:
 - a bag having a hollow interior defined by two sides meeting at opposite edges, a bottom and a top, with said edges and bottom sealed and said top at least partially open to receiving said;
 - a gellable hydrophilic material within said bag, said material becoming fully gelled within thirty seconds of said contact with said fluid when said is deposited in said bag, said gelation serving to essentially completely sequester said and prevent said fluid from thereafter being expelled from said bag;

funnel means within said interior and having an open top, said funnel means being secured to said bag at said top of said bag, and extending downwardly within said interior to a narrower open bottom for conduction of fluid entering said open top through said funnel means and into said bag, with the open bottom of said funnel being disposed intermediate between said top and bottom of said bag, said open bottom being free from attachment to said sides of said bag such that flow of any unsequestered fluid within said bag back toward said funnel means acts to close said funnel means to prevent escape of said unsequestered fluid from said bag; and

closure means for closing the top of said bag after introduction of said fluid into said bag.

'139 Patent 8:39-66.

The '139 Patent lists in its References Cited a publication called "J. C. Bealer, Dept. of the Air Force, Letter to [General Services Administration ("GSA")] dated Oct. 11, 1989." Mr. James Bealer was a Logistics Manager for the Air Force and Program Manager for the Air Force's Productivity, Reliability, Availability, and Maintainability ("PRAM") Office. PX 64.1 at 8; JX 49. Mr. Bealer led a study from late 1989 through September 1991, comparing American Innotek's products covered by the '139 Patent -- the *Brief Relief* and *Flight Extender* -- to the Piddle Pak with Sponge. JX 52; JX 179 at 401. Mr. Bealer's October 11, 1989 letter to GSA -- listed in the '139 Patent and available in the prosecution history -- reads in full:

1. The Productivity, Reliability, Availability and Maintainability (PRAM) Program Office will be funding a test of a new type disposable relief bag to replace the old messy and totally unsanitary relief bag (NSN 8105-00-922-9469). The new relief bag called "Brief Relief" will be fielded to all active flying installations who have requested help in finding a better bag.
2. There still seems to be some confusion as to who will be the final approving authority to implement this product. I believe the new relief bag will speak for itself.
3. The old type relief bag (NSN 8105-00-922-9469) does not meet Mil Spec Mil-B-83665B and in our opinion poses a health hazard to those using them. The new brief relief bag exceeds present Mil Specs and can be used by women.
4. Cost to the government will be 50 percent less and have a 20-year cost savings of \$3.3 million.
5. PRAM is presently working on revising the specification to upgrade the requirements and get a better bag in the field.

JX 179 at 401.

The referenced Mil-Spec B-83665B in paragraph 3 above is a military specification -- a United States Department of Defense ("DoD") standard used to provide a government contractor with a product's requirements to satisfy military needs. See 41 C.F.R. § 101-29.216-29.217.

Military standards are more informative than industry standards in that a military specification is a DoD requirement, whereas industry standards are voluntary. Compare 41 C.F.R. § 101.29.217 (defining a military specification for the Department of Defense Index of Specifications and Standards) with 41 C.F.R. § 101.29.218 (defining industry standards as “voluntary” for DoD).

Specifically, Military Specification Mil-B-83665B (“Mil-Spec B”) is a 1981 Department of Defense standard covering “the requirements for one type of disposable plastic bag suitable for the collection, retention, and temporary storage of urine.” JX 47 at G1378. Mil-Spec B provides an objective limit on the amount of leakage allowed in a military urine containment bag, prior to closing the bag, through an “inverted leak test.” Id. at G1381. The test provides:

4.4.2 Inverted leakage test. This bag shall be filled with a minimum of 550 [cubic centimeters] of water and, without closing, quickly inverted. There shall be no more than 30 [cubic centimeters] of liquid spilled from the opening during a one-minute period.

Id. According to Mr. Bealer’s 1989 letter to GSA, present in the ’139 Patent specification and prosecution history, Plaintiff’s *Brief Relief* product -- an embodiment of the ’139 Patent -- met and exceeded this Mil-Spec B leakage requirement. ’139 Patent References Cited; JX 179 at 401.

Discussion

Jurisdiction

This Court has exclusive jurisdiction over patent infringement actions against the Government under 28 U.S.C. § 1498(a). IRIS Corp. v. Japan Airlines Corp., 769 F.3d 1359, 1363 (Fed. Cir. 2014); Uusi, LLC v. United States, 110 Fed. Cl. 604, 609 (2013). Section 1498 provides in relevant part:

Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.

28 U.S.C. § 1498(a) (2012). Actions under § 1498 are limited to monetary damages. Advanced Software Design Co. v. Fed. Reserve Bank of St. Louis, 583 F.3d 1371, 1375 (Fed. Cir. 2009).

As the General Services Administration and Defense Logistics Agency purchased 981,250 Piddle Paks with Powder from NYCIB from April 8, 2005 to May 26, 2009, for military use, the Court has jurisdiction over the instant patent infringement action under 28 U.S.C. § 1498 for Defendant’s alleged use of a patented invention without authority from the Patent Owner, American Innotek.

Claim Construction

The Court held a Markman⁴ hearing in this case and issued its first claim construction opinion on May 24, 2013. American Innotek, 113 Fed. Cl. at 668. Since then, the Supreme Court ruled in Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc., that claim construction is not a pure question of law, but is a mixed question of fact and law. 135 S. Ct. 831, 840-41 (2015) (abrogating Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448 (Fed. Cir. 1998)). In Teva, the Supreme Court held that construction of the intrinsic written instruments of a patent -- the patent itself, the specification, and the prosecution history -- are questions of law, whereas construction based on extrinsic evidence, such as expert testimony or dictionaries, are issues of fact. Id. at 841. This change in legal standard does not affect the Court's prior claim construction. In its first claim construction opinion, the Court construed the following terms of the '139 Patent, all located in independent Claim 1 as follows:

Claim 1 term	Court's Construction⁵
"free from attachment to said sides of said bag"	free from attachment to said sides, but not necessarily free from attachment to the edges
"unsequestered fluid"	water or water-based liquids such as bodily fluids containing some hydrophilic material that have not yet gelled
"closure means for closing the top of said bag"	a clamp 34 or zipper closure 43, and equivalents thereof

American Innotek, 113 Fed. Cl. at 687.

Courts are not to construe claims until a sufficiently developed evidentiary record is established. See Apex Inc. v. Raritan Comput., Inc., 325 F.3d 1365, 1374 (Fed. Cir. 2003); see also CytoLogix Corp. v. Ventana Med. Sys., Inc., 424 F.3d 1168, 1172 (Fed. Cir. 2005) ("the [trial] court has considerable latitude in determining when to resolve issues of claim construction."). Here, the construction of the limitation "prevent escape" within Claim 1 of the patent was disputed after both the infringement trial and the Court's original claim construction decision. The Court therefore ordered supplemental briefing on the construction of this term and conducted another claim construction hearing limited to the "prevent escape" term.

⁴ Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996).

⁵ The Court's claim construction opinion also construed the term "particle sizes in the range of -40+120 Mesh U.S. Sieve Series" located in claims 5, 6, and 7 of the '139 patent. That term is no longer relevant to the Court's opinion because the parties stipulated to dismissal of Plaintiff's assertion of infringement with respect to these claims on January 10, 2014.

Construction of the Term “Prevent Escape”

Claim 1 recites:

A containment bag for a fluid comprising water or water-based liquid such as bodily fluids which comprises:

a bag having a hollow interior defined by two sides meeting at opposite edges, a bottom and a top, with said edges and bottom sealed and said top at least partially open to receiving said;

a gellable hydrophilic material within said bag, said material becoming fully gelled within thirty seconds of said contact with said fluid when said is deposited in said bag, said gelation serving to essentially completely sequester said and prevent said fluid from thereafter being expelled from said bag;

funnel means within said interior and having an open top, said funnel means being secured to said bag at said top of said bag, and extending downwardly within said interior to a narrower open bottom for conduction of fluid entering said open top through said funnel means and into said bag, with the open bottom of said funnel being disposed intermediate between said top and bottom of said bag, said open bottom being free from attachment to said sides of said bag such that flow of any unsequestered fluid within said bag back toward said funnel means acts to close said funnel means to prevent escape of said unsequestered fluid from said bag; and

closure means for closing the top of said bag after introduction of said fluid into said bag.

’139 Patent 8:39-66 (emphasis added).

The parties propose the following constructions:

Claim Term	Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
“prevent escape”	“avert, hinder or stop from doing something” Pl.’s Suppl. Claim Constr. Br. 4-5.	“wholly prevent escape” Def.’s Suppl. Claim Constr. Br. 1.

The crux of the parties’ dispute is whether the term “prevent escape” in the context of the “funnel means” in Claim 1 allows for any leakage of unsequestered fluid from the containment bag. Plaintiff’s position is that the ordinary meaning of the term “prevent” is not absolute and allows for some leakage. Plaintiff proposes that “prevent” should be construed as “avert, hinder, or stop.” Pl.’s Suppl. Claim Constr. Br. 4-5. Defendant conversely argues that “prevent” means to “wholly prevent” any leakage. Def.’s Suppl. Claim Constr. Br. 1.

Claim terms should be given their ordinary and customary meaning as used in the field of invention. Phillips v. AWH Corp., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). The ordinary and customary meaning is the meaning a claim term would have to a skilled artisan at the time of invention -- the effective filing date of the patent application. Phillips, 415 F.3d at 1313 (citing Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1116 (Fed. Cir. 2004)). A person of ordinary skill in the art is “deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” Id. “In some cases, the ordinary meaning of claim language . . . may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of widely accepted meaning of commonly understood words.” Id. at 1314. A claim can depart from its ordinary meaning only if the inventor has explicitly assigned it a separate meaning. Id. at 1316.

To construe claims, a court objectively looks at public sources, such as the patent itself, its prosecution history, or technical dictionaries available at the time, that show what a skilled artisan would have understood the disputed claim language to mean. Innova, 318 F.3d at 1116. In Phillips, the Federal Circuit clarified that courts should first review the “intrinsic” record of the patent. 415 F.3d at 1314-17. Intrinsic evidence consists of the patent claims, specification, and the patent’s prosecution history. Id. at 1314; IMS Tech., Inc. v. Haas Automation Inc., 206 F.3d 1422, 1433 (Fed. Cir. 2000). The most important source of evidence for construing patent claims are the claims themselves because they “define the invention to which the patentee is entitled the right to exclude.” Phillips, 415 F.3d at 1312 (internal citation and quotation marks omitted). The second most critical source of intrinsic evidence is the patent specification, which “contain[s] a written description of the invention and of the manner and process of making and using it” 35 U.S.C. § 112 ¶ 1.⁶ The “specification ‘is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term.’” Phillips, 413 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582)). The third source of intrinsic evidence is the prosecution history, which consists of “the complete record of the proceedings before the PTO and includes the prior art cited during examination of the patent.” Id. at 1317. The prosecution history is less useful in claim construction, however, because it can itself be ambiguous as it represents ongoing negotiations between the patent applicant and the PTO. Id.; see Inverness Med. Switz. GmbH v. Warner Lambert Co., 309 F.3d 1373, 1380-82 (Fed. Cir. 2002).

⁶ Section 112 of Title 35 of the United States Code was revised as of September 16, 2011, to designate previously undesignated paragraphs, and to conform terminology with changes made in other parts of Title 35. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 4(c), 125 Stat. 284, 296 (2011). These changes do not alter 35 U.S.C. § 112 with respect to the issues addressed in this case. Nevertheless, the pre-September 16, 2012 version of § 112 applies here because the ’139 Patent issued prior to that date and the Leahy-Smith Act provides that the amendments apply only to new patent applications. See § 4(e), 125 Stat. at 297 (“The amendments made by this section shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act and shall apply to any patent application that is filed on or after the effective date.”).

After consideration of the intrinsic evidence, if a court still finds the claim term to be ambiguous, it can look to extrinsic evidence which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” Markman v. Westview Instruments, Inc., 52 F.3d 967, at 980 (Fed. Cir. 1995) (internal citations omitted). However, such external evidence is “less significant than the intrinsic record in determining ‘the legally operative meaning of claim language.’” C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) (quoting Vanderlande Indus. Nederland BV v. Int’l Trade Comm’n, 366 F.3d 1311, 1318 (Fed. Cir. 2004)).

Ordinary Skill in the Art

Defendant’s expert, Richard Moran,⁷ testified that a person of ordinary skill in the field of disposable urine containment devices, would be either “a person with a degree in engineering or the sciences with one to three years of experience in the field, or a person without a degree with three to five years of experience.” Tr. 662-63. Plaintiff does not offer a competing definition or present contrary evidence. As such, the Court adopts Defendant’s un rebutted definition of a person having ordinary skill in the art. Sparton Corp. v. United States, 89 Fed. Cl. 196, 208 (2009) (citing Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V., 528 F.3d 1365, 1380 (Fed. Cir. 2008)). A person of ordinary skill in the art would assess the ’139 Patent as of its filing date on February 15, 1991.

Ordinary and Customary Meaning

The parties dispute the construction of the “prevent escape” limitation within the context of the “funnel means” component of independent Claim 1, in particular on how effectively the “funnel means” is able to close and entrap unsequestered fluid within the containment bag. Both parties claim that the term “prevent” should be given its ordinary and customary meaning, but differ as to what that meaning is. Plaintiff asserts that the term “prevent” does not require construction and that the funnel structure described in Claim 1 does not stop all leakage of fluid from the inner containment bag. Pl.’s Suppl. Claim Constr. Br. 4 (“[T]he word ‘prevent’ means prevent. It does not mean stop.”). If the Court finds claim construction to be required, Plaintiff argues that “the word ‘prevent’ in the phrase ‘to prevent escape of said unsequestered fluid’ means ‘to avert, hinder or stop the escape of said unsequestered fluid.’” Id. at 4-5. Defendant counters that the ordinary and customary meaning of prevent is absolute, such that no fluid can leak from the inner containment bag, and thus “prevent” should be construed as “wholly prevent.”

As both parties’ readings of “prevent” are plausible, the Court finds the term to be ambiguous and require construction. Deering Precision Instruments, LLC v. Vector Distrib. Sys., 347 F.3d 1314, 1323 (Fed. Cir. 2003) (holding that where a term “is capable of multiple

⁷ Mr. Moran received a degree in mechanical engineering from Yale University in 1953. Mr. Moran spent almost 40 years working at Procter & Gamble, where he worked with one-way valves in a pulp mill, diaper products, adult incontinence devices, tampons, and super-absorbent polymers. Following his retirement from Procter & Gamble in 1994, Mr. Moran started a consulting business that dealt entirely with the “disposables and nonwovens industry.” DX 101. Mr. Moran was accepted as an expert in the field of disposable absorbent products used for the collection and containment of human bodily fluids, without objection. Tr. 581-82.

interpretations, we turn to the intrinsic evidence to determine which interpretation should be adopted”); Protective Optics, Inc. v. Panoptx, Inc., 458 F. Supp. 2d 1053, 1061 (N.D. Cal. 2006) (requiring construction of the term “prevent” with respect to eyewear that “prevents the passage of solids and liquids” because of “the range of meanings associated with troponyms of ‘prevent’” including “deflect, avert, obstruct, hinder, thwart, frustrate, baffle, stop and block”).

The Claims

Claim construction starts with the claims themselves because “it is the claims that measure the invention.” SRI Int’l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc) (emphasis in original); see Phillips, 415 F.3d at 1314. Claim 1, as a whole, supports a construction of the term “prevent” that would allow some degree of escape, because Claim 1 requires three different mechanisms of limiting leakage of fluid -- the gellable hydrophilic material, the funnel means, and the closure means, and if any one of these three means “wholly” prevented escape of fluid, then the other two would be redundant to the claim. See Phillips, 415 F.3d at 1314 (“[T]he context in which a term is used in the asserted claim can be highly instructive.”).

The three separate limitations that combine to create a potentially leakproof product are described in Claim 1 as:

1. a gellable hydrophilic material capable of becoming fully gelled within 30 seconds of contact with fluid, “said gellation serving to essentially completely sequester said fluid and prevent said fluid from thereafter being expelled from said bag;”
2. a funnel means constructed “such that flow of any unsequestered fluid within said bag back toward said funnel means acts to close said funnel means to prevent escape of said unsequestered fluid from said bag;” and
3. a closure means “for closing the top of said bag after introduction of said fluid into said bag.”

’139 Patent 8:39-64.

As the claimed urine containment bag is required to have these three limitations -- the hydrophilic material, funnel means, and closure means -- and were any of these three limitations to perform identical functions as another, the redundant limitation would be unnecessary to the invention. For example, if the funnel means successfully prevented all bodily fluid from escaping from the bag, the closure means would be unnecessary. Construing a claim in a way that renders a limitation unnecessary fails to take into account the context of the claim as a whole. ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1088 (Fed. Cir. 2003) (“While certain terms may be at the center of the claim construction debate, the context of the surrounding words of the claim must also be considered in determining the ordinary and customary meaning of those terms.”). Accordingly, if the funnel means prevented all escape of fluid, the other two means would be superfluous to the goal of creating a leakproof bag.

Indeed, Defendant recognizes that the funnel means could potentially fail to stop the escape of unsequestered fluid from the containment bag, thus necessitating the closure means. Def.’s

Suppl. Claim Constr. Br. 8 (“Although the closure means is capable of stopping the escape of the contents from the bag’s interior chamber, it would only need to do so in the event that the funnel means were to fail. Instead, the primary role played by the closure means is stopping the spillage of bodily fluids that remained in the funnel structure and thus never came into contact with the hydrophilic material.”). In other words, the funnel means alone does not, in every instance, stop all bodily fluid from escaping the interior of the chamber. Id. (citing Tr. 119-21).

Further the term “prevent” is used twice in Claim 1, once to claim the action of the gellable hydrophilic material and once to claim the action of the funnel means. When a term appears twice in the same claim, a Court should construe that term consistently. See Digital Biometrics, Inc. v. Indentix, Inc., 149 F.3d 1335, 1345 (Fed. Cir. 1998) (“[T]he same word appearing in the same claim should be interpreted consistently.”) (citing Fonar Corp. v. Johnson & Johnson, 821 F.2d 627, 632 (Fed. Cir. 1987)). The ’139 Patent does not support a construction of “prevent” in the context of the gellable polymer to mean “wholly prevent.” Rather, the specification describes the gellable polymer, in conjunction with the closure means, to only result in a urine containment bag that is “virtually impervious to accidental spillage of the contents,” that permits a “minimal possibility” of the bag’s contents spilling. ’139 Patent 8:10-22; ’139 Patent Abstract. Defendant agrees, noting in its supplemental claim construction briefing that “[t]he hydrophilic material has limitations, however, in that it does not stop the escape of fluids – be it unsequestered or pure bodily fluids.” Def.’s Suppl. Claim Constr. Br. 8.

That the gellable hydrophilic material does not “wholly prevent” escape of the fluid comports with the claim language describing the gellable hydrophilic material as only capable of “essentially” completely sequestering the bodily fluid in the bag, while leaving some fluid “unsequestered,” and thus potentially escapable. ’139 Patent 8:46-51, 61. As the term “prevent” in the context of the gellable hydrophilic material allows for leakage, it would be inconsistent for the Court to construe the term “prevent” as “wholly preventing” leakage of unsequestered fluid from the containment bag in the context of the funnel means. See Omega Eng’g, Inc. v. Raytek Corp., 334 F.3d 1314, 1334 (Fed. Cir. 2003) (“[T]he same claim term in the same patent or related patents carries the same construed meaning.”); Digital Biometrics, 149 F.3d at 1345.

The Specification

The claim words must also be read in light of the patent specification. Phillips, 415 F.3d at 1315 (the patent’s “specification ‘is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term.”) (quoting Vitronics, 90 F.3d at 1582). The ’139 Patent specification twice indicates that the funnel acts to “restrict expulsion” of fluid from the containment bag. ’139 Patent Abstract, 2:56-59. The Abstract states that the containment bag has “preferably a funnel structure within the bag to channel said bodily fluids into the interior and to restrict expulsion of bodily fluids from the interior prior to sequestration [by the gellable hydrophilic material].” ’139 Patent Abstract (emphasis added). The Summary of the Invention similarly states that “[p]referably there are also means disposed within the bag for channeling the bodily fluids into the interior and for restricting expulsion of the bodily fluids from the interior prior to sequestration of the bodily fluids.” ’139 Patent 2:56-59 (emphasis added). The term “restrict” does not connote a meaning of prevent that is absolute -- as in “wholly prevent” -- but instead suggests that the expulsion of fluid from the containment bag should be limited or controlled by the funnel means.

The Patent Abstract further states that the containment bag as a whole functions with a “minimal possibility that the bodily fluids will become spilled or otherwise expelled from the bag.” ’139 Patent Abstract (emphasis added). The Abstract thus recognizes that even the bag as a whole and not just the funnel means component would not completely prevent spillage.

Similarly, the specification section on Describing the Preferred Embodiments of the ’139 Patent, states:

The advantage of the present invention is over existing types of urine and other waste collection and disposal bags is evident. The presence of the rapidly gelling material allows for the completed collection and sequestration of the bodily fluids within a matter of seconds such that the bag of collected bodily fluids almost immediately becomes completely free of the possibility of leakage or spillage of any of the bodily fluids. Thus, the bag can be immediately closed as with the clamp 34 or the zipper closure 43 and be set aside for subsequent safe and convenient disposal. In this condition the bag is virtually impervious to accidental spillage of the contents.

’139 Patent 8:10-22 (emphasis added).

The specification excerpt above describes the preferred embodiment to be only “virtually impervious to accidental spillage” even after the final “closure means” is implemented. *Id.* at 8:21-22. Given the specification’s description of the preferred embodiment of having a final condition of “virtually impervious” to spillage once all three means combined are implemented, “prevent escape” of a single means standing alone -- the funnel means -- can only result in a bag that is at most “virtually impervious.” Defendant’s proposed construction of “prevent escape” in the context of the funnel means to mean “wholly prevent escape” would exclude the preferred embodiment that describes the invention as “virtually,” not completely, “impervious to accidental spillage.” *Id.* at 8:21-22; see *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1311 (Fed. Cir. 2014) (“In particular ‘where claims can reasonably [be] interpreted to include a specific embodiment, it is incorrect to construe the claims to exclude that embodiment, absent probative evidence to the contrary.’”) (quoting *Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1277 (Fed. Cir. 2008) (alternation in original)). In sum, given the descriptions in the specification indicating that there could be some minimal escape of spillage or expulsion of fluid, the “prevent escape” limitation should be construed to allow for some leakage.⁸

⁸ Defendant argues that Plaintiff made a series of admissions acknowledging that the prevent escape limitation indicates “wholly prevent escape.” For example, Plaintiff stated during the claim construction hearing that “some of the fluid gets caught behind the side of the funnel and the side of the bag, and the concept is that that pressure is supposed to help stop the flow of liquid out of the bag.” Def.’s Proposed Findings of Fact ¶ 132 (“DPF”). Plaintiff’s description that the funnel means is “supposed to help stop the flow” is not tantamount to an admission that the funnel means “wholly prevents” the flow of fluid from the containment bag. As such, what Defendant characterizes as admissions do not override the express language of the claims and specification, as well as Defendant’s own expert’s testimony, that allow for the possibility of leakage of fluid from the containment bag.

The Prosecution History⁹

The prosecution history of the patent consists of “the complete record of the proceedings before the PTO and includes the prior art cited during examination of the patent.” Phillips, 415 F.3d at 1317. A patent’s prosecution history “can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution. . . .” Id. But prosecution history can be ambiguous and thus less useful in claim construction. Id.; Inverness Med. Switz. GmbH, 309 F.3d at 1382. However, if an inventor limited the claims during prosecution, it cannot later “recaptur[e] through claim interpretation specific meanings disclaimed during prosecution” to overcome prior art. Omega Eng’g, Inc., 334 F.3d at 1323; Purdue Pharma L.P. v. Endo Pharms. Inc., 438 F.3d 1123, 1136 (Fed. Cir. 2006).

Defendant argues that American Innotek narrowed the scope of Claim 1 during prosecution in a radical way – changing its characterization of the funnel means from allowing some leakage of fluid to “wholly preventing escape.” Defendant has two bases for its argument. First, Defendant argues that the Applicants represented in remarks for a claim amendment that the ’139 Patent’s funnel means closed in order to overcome a rejection in the prior art based on United States Patent No. 3,403,715 (“Trudel”). The Applicants’ remarks stated:

None of the cited references or prior art shows a one-way valve bag structure which prevents release of fluid by having the fluid itself serve to prevent its own leakage by closing the channel or funnel into the bag. The Trudel bag remains somewhat open and allows leakage. . . .

Def.’s Suppl. Claim Constr. Br. 5-6 (emphasis added). Defendant’s position is that this statement represents a clear and unmistakable disclaimer that the ’139 Patent’s funnel means is capable of closing and blocking all leakage of fluid from the containment bag, unlike Trudel, which “remains somewhat open and allows leakage.” Id.

Second, Defendant argues that during an Examiner interview, the Applicants demonstrated the operation of the device, leading the Examiner to grant the ’139 Patent, over Trudel. Following the Examiner interview, the Applicants submitted final remarks, stating:

Applicants have incorporated language which defines the funnel as being closed by the back flow of fluid, which effectively seals the funnel and prevents escape of the fluid from the interior of the bag, regardless of the orientation of the bag The actual operation of the claimed structure was demonstrated during the aforementioned interview.

JX 179 at 316-17, 330 (emphasis added); Def.’s Post Trial Br. 25. Defendant posits that in these two statements, the Applicants represented to the Examiner, in their final remarks before allowance, that the funnel closes due to backflow of fluid and results in a leakproof urine containment bag to overcome the prior Trudel rejection. From this, Defendant contends that the

⁹ The Court reviewed the ’139 Patent prosecution history in its claim construction opinion, American Innotek, Inc., 113 Fed. Cl. at 672-74.

Applicants explicitly disclaimed, and narrowed the scope of, the funnel means in the '139 Patent to only cover an absolutely leakproof urine containment bag.

For a court to narrow a claim's meaning, the disclaimer must be "clear and unmistakable." Purdue, 438 F.3d at 1136. A "clear and unmistakable disclaimer" must be an explicit argument that "a claim possesses a feature that the prior art does not possess in order to overcome a prior art rejection," and then the "argument may serve to narrow the scope of otherwise broad claim language." Seachange Int'l., Inc. v. C-COR, Inc., 413 F.3d 1361, 1372-73 (Fed. Cir. 2005) (quoting Rheox, Inc. v. Entact, Inc., 276 F.3d 1319, 1326 (Fed. Cir. 2002)); Omega Eng'g, Inc., 334 F.3d at 1326.

In the instant case, the Court finds Defendant's alleged prosecution history disclaimer to be ambiguous and not enlightening on the meaning of "prevent escape" in the context of the funnel means. Defendant has not established that Plaintiff's statements made during the Examiner interview and claim amendment process constitute a "clear and unmistakable" disclaimer of the scope of the funnel means in Claim 1 of the '139 Patent.

Following the Examiner's rejection of all claims, the Applicants filed the '354 Application on February 15, 1991 -- which eventually issued as the '139 Patent -- with Claim 38, stating:

funnel means within said interior and having an open top integrated and substantially coextensive with said top of said bag, and extending downwardly to an open bottom within said interior for conduction of fluid entering said open top through said funnel means and into said bag, with the open bottom of said funnel means being disposed intermediate between said top and bottom of said bag, said open bottom being spaced apart from said sides of said bag and adapted to prevent backflow of fluid entering said bag through said funnel means;

JX 179 at 263, 276, 281-82 (emphasis added).

On May 3, 1991, the Examiner again rejected all claims as obvious based on three prior art references: Trudel, U.S. Patent No. 3,297,152 ("Corrella"), and U.S. Patent No. 4,179,367 ("Barthell"). Id. at 301, 303-05. The Examiner explained what each of these three patents taught, and how each patent read on Claim 38, and its dependent Claim 39:

The claims [38-49, 55 and 56] are considered to be met by Trudel except that Trudel does not disclose placing a hydrophilic material within the bag to sequester bodily fluids. Trudel also does not disclose making the funnel means as completely separate structure.

Barthell et al. teaches placing an intestinal content or urine thickening agent within an excrement collection bag for the purpose of "sloshing of contents" in the bag. It would have been obvious to one having ordinary skill in the art to provide the Trudel bag with a hydrophilic material in order to gelate bodily fluids deposited in the bag, taught to be desirable by Barthell et al. As a note, Barthell et al. teaches using the water-swelling polymer acrylonitrile. Barthell et al. also includes perfume materials in order to reduce odors.

* * *

Corrella et al. teaches funnel structure where the open bottom is spaced apart from the sides on an analogous bag in order to alleviate leaking problems associated with bags whole funnel structures rely on side tensioning of a filled bag to close it. It would have been obvious to one having ordinary skill in the art to replace the funnel structure of Trudel with the non-integral funnel structure of Corrella et al. in order to prevent backflow of fluid entering the bag through the funnel structure, taught to be desirable by Corrella et al.

Id. at 303-05 (emphasis added).

On July 25, 1991, following this obviousness rejection, the Examiner held an interview with inventor Cassidy and his attorney, Mr. Neil Martin. Id. at 307. Following the interview, the Examiner filed an Interview Summary Record contemporaneously memorializing the interview and reflecting that a “model of invention was tested using water,” stating in full:

Claim 39, re-written with modification to recite that liquid can get behind at least a portion of the walls of the funnel to close funnel would be allowed upon commercial success showing. Claim reciting specific particle size appears allowable since such achieves faster gelling time than Barthell et al. Argument re present claims can also be presented if desired.

JX 179 at 307. In his Summary, the Examiner did not indicate whether the prototype bag had any leakage, or find that independent Claim 38 and its dependent claims had to be rewritten to require complete prevention of leakage. Nor did the Examiner express that the funnel means itself stopped all unsequestered fluid from leaving the interior of the containment bag. Rather, the Examiner only noted how the funnel operates based on the single test using water performed by inventor Cassidy, in which he observed that fluid is able “to get behind a portion of the funnel to close the funnel.” Id.¹⁰

Following the interview, the Applicants amended their claims by cancelling Claim 39, which depended on Claim 38, and substituted it with independent Claim 62. Id. at 309, 316. Claim 62 stated that the funnel means was constructed “such that flow of any unsequestered fluid within said bag back toward said funnel means acts to close said funnel means to prevent escape of said

¹⁰ Over 20 years later, in his deposition in this case, inventor Cassidy’s attorney, Mr. Neil Martin (also Plaintiff’s expert in this case) testified about this test:

Mr. Cassidy filled [a prototype] bag to capacity with water and immediately inverted the filled bag on the Examiner’s desk. At this stage of gelation, there was clearly unsequestered liquid in the bag. However, none of the liquid leaked out of the bag and the [examiner’s] desk and papers were completely dry.

PX 57 at G5884. Because this description of the interview occurred in a deposition two decades later in the context of this litigation where the patent’s validity is at stake, the Court does not consider it part of the prosecution history. The testimony is not a contemporaneous statement by the Applicants available to the public before 1991.

unsequestered fluid from said bag.” Id. at 309. Claim 39 had previously provided that the funnel means had been “adapted to prevent backflow of fluid entering said bag through said funnel means.” Id. at 281-82. The Applicants could have, but did not, assert that the bag would be leakproof. Instead, the Applicants submitted remarks accompanying the addition of Claim 62, stating:

Applicants have incorporated language which defines the funnel as being closed by the back flow of fluid, which effectively seals the funnel and prevents escape of the fluid from the interior of the bag, regardless of the orientation of the bag The actual operation of the claimed structure was demonstrated during the aforementioned interview.

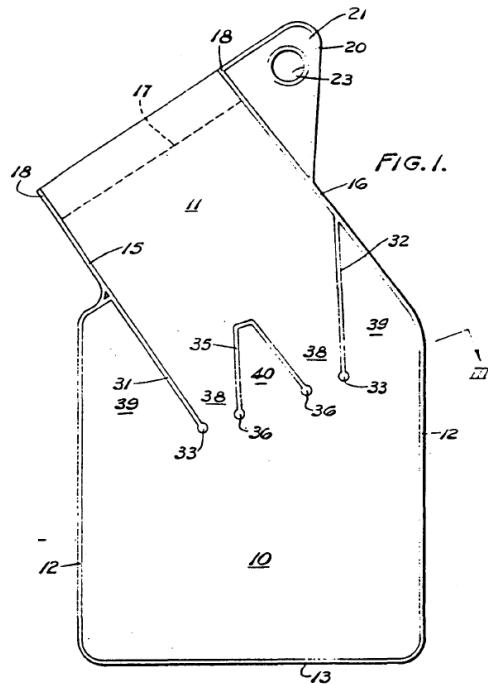
Id. at 316-17 (emphasis added).

Plaintiff also amended Application Claims 38 and 57¹¹ and explained how the amendment set the invention apart from the Trudel patent considered during the interview:

None of the cited references or the prior art products shows a one-way valve bag structure which prevents release of fluid by having the fluid itself serve to prevent its own leakage by closing the channel or funnel into the bag. The Trudel bag remains somewhat open and allows leakage, as was demonstrated at the aforementioned interview. While the Trudel patent contends that as fluid accumulates in the pockets 39 and 40, the fluid will eventually serve to stretch the bag and force the openings 38 closed, it was demonstrated at the interview that there is still a significant amount of leakage of fluid moving toward the pockets 39 and 40 while the pockets are filling, since it is obvious that the fluid moving in that direction also flows through the openings 38 until such time as sufficient fluid has accumulated in the pockets to begin closing the openings 38. Even then, significant leakage continues to take place, since in practice it is found that the amount of fluid in the pockets 39 and 40 is never becomes sufficient to place enough force on the fabric of the Trudel bag to fully close the openings 38 and prevent leakage of fluid.

Id. at 319 (emphasis added). The following Figure 1 from the Trudel specification illustrates the Applicants’ remarks:

¹¹ Independent Application Claim 57 was nearly identical to Claim 38 except that it additionally included a “stiffening means” located on the top of the containment bag to hold “said top into an opened position.” JX 179 at 315.



JX 179 at 100. Application Claim 62 was allowed as Claim 1 of the '139 Patent. Application Claims 38 and 57 were not allowed. *Id.* at 327-28.¹²

Defendant argues that Plaintiff's remarks accompanying the amendment to Application Claims 38 and 57, represent that the embodiment of the '139 Patent would be clearly and unmistakably leakproof after the funnel means is effected and before the closure means is implemented. Defendant reasons that the funnel limitations in Claims 38 and 57 -- and similar language in Claim 62 -- were, in the Applicants' view, superior to the funnel valves in Trudel because their '354 Application's funnel means stopped leakage and thus rendered those claims patentable over Trudel. *Id.* at 319. Although Applicants' statements accompanying the amendment to '354 Application Claims 38 and 57 relate to the same "funnel means" language added to Application Claim 62, they do not "rise to the level of "a clear and unmistakable disavowal of scope during prosecution." *Purdue Pharma*, 438 F.3d at 1136. *Cf. Uship Intellectual*

¹² Defendant relies heavily on statements made by counsel during the *Markman* hearing and statements in the expert report of Mr. Martin as evidence that Application Claim 62 was only allowed because the embodiment tested in the examiner interview was leakproof. This reliance is misplaced. Plaintiff's attorney argument and expert report would not have been available to and thus provide notice to competitors of the boundaries of the '139 Patent, because these representations were not publicly accessible. See *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("[C]ompetitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention, and, thus, design around the claimed invention."). Allowing the public record to be altered or changed with evidence introduced at trial over 20 years after the '139 Patent issued would defeat the purpose of construing claims based on the public record from the perspective of a skilled artisan at the time of the patent's issuance that this Court is tasked with accomplishing here. See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005).

Props., LLC v. United States, 714 F.3d 1311, 1315 (Fed. Cir. 2013) (finding a prosecution history disclaimer that all steps in a method for mailing parcels could only be performed by a machine, not by human, after the applicant explicitly represented that reciting “‘using an automated shipping machine’ in the preamble [of the patent claims] is equivalent to ‘specifically reciting’ that phrase at each step of the method” to overcome a restriction requirement rejection).

Here, the Applicants could have, but did not, explicitly state that their product was leakproof throughout the prosecution history. Rather, the Applicants discussed the operation of the funnel means -- stating that the liquid itself was “serving to prevent its own leakage by closing the channel or funnel into the bag” -- not that the funnel means achieved a leakproof solution. JX 179 at 319. In other words, the Applicants differentiated Trudel, saying that Trudel’s funnel mechanism had “a significant amount of leakage of fluid” because fluid was not operating to close the funnel until the pockets between the funnel openings filled, as illustrated by the openings at 38, 39, and 40 in Figure 1 of Trudel. In contrast, the Applicants argued that the funnel means in the ’139 Patent improved on Trudel by defining the funnel as “being closed by the back flow of fluid.” While this claim amendment overcame the obviousness rejection in view of Trudel, it did not either represent a complete closure of the funnel prior to any fluid escaping or characterize this operation of the funnel means as achieving a leakproof solution.

In their remarks amending Claim 62, the Applicants also state the following phrase: the “funnel as being closed by the back flow of fluid, which effectively seals the funnel and prevents escape of the fluid from the interior of the bag.” Id. at 316-17 (emphasis added). This phrase does not suggest an absolute leakproof solution, and does not indicate that no leakage occurs under all circumstances in which the bag is used according to the specification -- including blood collection and vomit. ’139 Patent 1:48-60. Nor does Defendant’s reliance on the Examiner interview help its effort to show that Applicants somehow represented that the ’139 Patent’s containment bag’s funnel means wholly prevented any leakage. The best evidence, the contemporaneous Examiner’s Summary of the Interview, does not indicate that the Examiner understood either that the funnel means operated in a leakproof fashion or that the Examiner allowed the ’139 Patent because the Applicants had described the funnel means as wholly preventing the escape of fluid. Defendant has thus not established that the Applicants made a “clear and unmistakable disclaimer” that the funnel means alone was leakproof. See Omega Eng’g Inc., 334 F.3d at 1326.

The concept of being leakproof is not difficult to convey in the English language. Defendant’s cited representations from a murky prosecution history do not overcome the multiple references in the Claims and specification that there could be some spillage or leakage in the patented invention. ’139 Patent Abstract, 2:56-59, 8:10-22, 8:39-66. In sum, three points lead the Court to reject Defendant’s disclaimer argument. First, the Applicants never explicitly said during or after the Examiner interview that the funnel means resulted in a perfectly leakproof bag prior to the closure means of the bag being implemented. Second, the Examiner never clearly indicated that he understood the closing of the funnel means to lead to a leakproof bag before allowing the claims. Third, the Applicants in amending their claim to overcome an obviousness rejection only represented that the funnel means in the ’139 Patent was far superior to the funnels in Trudel, not that the funnel means prevented all leakage of fluid from the bag. As such, the Court finds the Applicant’s statements in the prosecution history to be ambiguous -- not clear and unmistakable - - on whether the funnel means absolutely “prevents escape” of fluid from the containment bag.

Thus, the Court declines to significantly narrow the scope of the funnel means in Claim 1 of the '139 Patent to "wholly prevent escape" of unsequestered fluid from the interior of the bag.

Extrinsic Evidence

Extrinsic evidence consists of public sources of knowledge, such as technical dictionaries, expert testimony, and construction of the same term by other courts, that are external to the patent-in-suit but provide the Court with an objective understanding of a claim term's meaning at the time of invention. Here, the District Court's construction of "prevent" in Protective Optics corroborates this Court's understanding that the funnel means does not "wholly prevent" or absolutely stop leakage of fluid from the containment bag. 458 F. Supp. 2d 1053 (N.D. Cal. 2006). This understanding is further supported by Defendant's expert's trial testimony on how different types of bodily fluids affect leakage.

The Court finds the usage of the word "prevent" here to be similar to the usage of "prevent" in a district court case, Protective Optics, that addressed the term prevent in the context of fluids. 458 F. Supp. 2d 1053. In Protective Optics, the patent at issue involved an eye shielding system "to prevent liquids and solids from entering the face area behind eyeglasses." 458 F. Supp. 2d at 1055. The construction there centered on whether "prevent" required the edge of the eye shield to "absolutely prevent the passage of materials" and fluid in particular "between the face and shield." Id. at 1061-62. The District Court declined to adopt the construction of "absolutely prevent" because the specification as a whole indicated "that the eye shield system is not intended to be perfect," based on the language "adequately protect" in the patent abstract. Id. at 1062. The court further noted that "[w]here a claim is expressed in general descriptive words, the court will not put 'a narrowing modifier before an otherwise general term that stands unmodified in a claim.'" Id. (citing Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1249-50 (Fed. Cir. 1998)). The District Court thus found the proper construction of "prevent" to be "substantially stop the passage of solids and liquids." Id.

Here, the '139 Patent specification, as discussed above, also indicates that the urine containment bag is not intended to be perfect, but tolerates a "minimal possibility that the bodily fluids will become spilled or otherwise expelled from the bag." '139 Patent Abstract. As such, here as in Protective Optics, the Court declines to add the Government's narrowing modifier of "wholly" before the otherwise general term "prevent" that stands unmodified in Claim 1. See 453 F. Supp. 2d at 1062; see also Renishaw, 158 F.3d at 1249.

Further, as a matter of extrinsic evidence, the prior art Corrella patent, present before the Examiner during the prosecution of the '139 Patent uses the term "prevent" in describing the funnel as alleviating leakage of fluid from its analogous bag, stating:

It is also an object of the present invention to provide a package or a container of this general type having a valve controlled inlet passage through which water or any other fluent substance may be easily introduced into the package but which serves to prevent accidental escape of the package contents through the passage.

JX 179 at 160 (emphasis added). As this similar prior art patent uses the term "prevent" in the context of "alleviating" leakage, not absolutely stopping leakage, the Court should do the same here. In re Cortright, 165 F.3d 1353, 1358 (Fed. Cir. 1999) ("Prior art references may be indicative

of what all those skilled in the art generally believe a certain term means . . . [and] can often help to demonstrate how a disputed term is used by those skilled in the art.”) (quoting Vitronics, 90 F.3d at 1584) (alterations in original)).

In a similar vein, the extrinsic evidence of Mr. Moran’s expert testimony militates against concluding that prevent should be construed to mean “wholly prevent.” The Court recognizes that Mr. Moran testified during trial that there may be cases in which embodiments of the ’139 Patent do “wholly prevent” any fluid from leaving the body portion of the bag. Tr. 677-80. For example, when water is used as the “fluid,” the superabsorbent polymer reacts both faster and more effectively. Tr. 684. Mr. Moran in fact performed a test of the Piddle Pak with Powder using water that resulted in no leakage -- similar to the test during the Examiner-conducted interview. Id.; PX 65.1. However, the ’139 Patent is not limited to water, but includes fluids that are “water-based liquid such as bodily fluid.”¹³ ’139 Patent 8:39-40. Mr. Moran testified that the higher the salinity of the fluid, the less capable the hydrophilic absorbent is of fully sequestering the fluid, and thus leakage can increase. Tr. 678 (Q: So, your answer is yes, [the Piddle Pak with Powder] would cause more leakage with salt water? Mr. Moran: Yes.). Moreover, other aspects of the fluid affect leakage such as temperature, and rate of input into the bag. Id. at 677-78, 680, 688-89. As Defendant’s construction would ignore this reality of how the gellable polymer reacts to different types of fluid which in turn effects how the funnel operates -- as its own expert testified -- the Court declines to adopt a narrow construction of the term “prevent escape” to mean “wholly prevent escape.”

The Court’s Construction

Here, the Court need only rely on the intrinsic evidence to understand that “prevent escape” in the context of the “funnel means” limitation in Claim 1 of the ’139 Patent does not mean to block all leakage of fluid from the containment bag, a conclusion also supported by extrinsic evidence. Accordingly, the Court finds that the phrase “prevent escape,” should be construed as “substantially prevent escape” to reflect that the prevention of leakage in the ’139 Patent is not perfect, but allows for minimal leakage. The Court adopts the modifier “substantially” for the same reasoning as the court in Protective Optics. 458 F. Supp. 2d at 1062. “Substantially,” in the context of claim construction, is “a meaningful modifier implying ‘approximate’ rather than ‘perfect.’” Liquid Dynamics Corp. v. Vaughn Co., Inc., 355 F.3d 1361, 1368 (Fed. Cir. 2004) (citing Cordis Corp. v. Medtronic AVE, Inc. 339 F.3d 1352, 1361 (Fed. Cir. 2003)).

¹³ Plaintiff emphasizes the fact that Mr. Moran used salt water, not urine, in his testing of the Piddle Pak with Powder to argue that Mr. Moran’s testing was somehow unreliable. Mr. Moran’s methods, however, follow the direct language of the patent. In the preamble to Claim 1, the patent recites that the purpose of the invention is to contain “fluid comprising water or water-based liquid such as bodily fluid.” ’139 Patent 8:39-41. Not only is a 1% saltwater solution the well-recognized substitute for urine in the testing of sanitation products, but saltwater is itself a “water-based liquid,” within the scope of Claim 1. Tr. 690 (Mr. Moran noting that using salt water in lieu of urine for testing is “pretty standard in the business”).

Indefiniteness

Defendant argues that Plaintiff's construction of "prevent escape" to allow for some leakage of unsequestered fluid would render Claim 1 indefinite because there is no limit specified to the amount of potential leakage. Def.'s Post-Trial Br. 29 ("The claims, when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art.") (quoting Interval Licensing LLC v. AOL, Inc., 766 F.3d 1364, 1371 (Fed. Cir. 2014)). Defendant contends that because the intrinsic record does not define how much leakage would be allowed within Claim 1, a person of ordinary skill in the art would not be able to determine the metes and bounds of the invention. The Court rejects this argument. The '139 specification contains an explicit reference to a 1989 letter from Mr. James Bealer, head of the Air Force PRAM study, to the General Services Administration stating that the urine containment bag embodied in Plaintiff's *Brief Relief* product exceeded the Mil-Spec B requirement, which contained a precisely defined limit on the permissible leakage. In addition because the specification itself references that the product would be used by the military, Mil-Spec B would be considered by a skilled artisan as a Department of Defense standard for military use without being explicitly repeated in the patent. It is established that "well known industry standards need not be repeated in a patent." Wellman, Inc. v. Eastman Chem. Co., 642 F.3d 1355, 1367 (2011) (finding a skilled artisan's awareness of an industry standard to weigh against a finding of indefiniteness) (citing Koito Mfg. Co. v. Turn-Key-Tech, LLC, 381 F.3d 1142, 1156 (Fed. Cir. 2004)).

As the Supreme Court explained, "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2124 (2014). An inventor also "need not explain every detail because a patent is read by those of skill in the art." Wellman, 642 F.3d at 1367. Here, Mil-Spec B was the Department of Defense standard for selling urine containment bags to the Government for military personnel. See Tr. 468 (when developing the Piddle Pak with Powder the NYCIB "went to [its] purchasing person and said, we need a product that would meet the military specification where the mil specs said that it needed to be able to absorb up to 500 cubic centimeters, I believe, of liquid.").

Mil-Spec B, the military specification in effect by 1981, provided a definitive limit on the amount of leakage of fluid allowed by a urine containment bag prior to being closed. JX 47. In its recitation of the inverted leakage test, Mil-Spec B provides:

4.4.2. Inverted leakage test. The bag shall be filled with a minimum of 550 [cubic centimeters] of water and, without closing, quickly inverted. There shall be no more than 30 [cubic centimeters] of liquid spilled from the opening during a one-minute period.

JX 47 at 1381.

The prosecution history reflects that the '139 Patent was designed for military use by the Air Force and Navy, and a skilled artisan would have been aware of the MIL-Spec B standard prior to the filing of the patent application. See Wellman, 642 F.3d at 1367. Not only was Mil-Spec B publicly available before February 1991, but references to the military requirements were considered by the Examiner in his review of the '139 Patent. The '139 Patent's listing of references

includes Mr. Bealer's Letter to GSA as a publication considered during prosecution detailing that Plaintiff's product, the *Brief Relief*, not only met but exceeded the requirements of Mil-Spec B:

The old type of relief bag (NSN 8105-00-922-9469) does not meet Mil Spec Mil-B-836658 [MIL-Spec B] and in our opinion poses a health hazard to those using them. The new brief relief bag exceeds present Mil Specs and can be used by women.

JX 179 at 372. This reference, located on the face of the '139 Patent in the References Cited and included in the prosecution history, would inform a skilled artisan that the '139 Patent would at a minimum meet the Mil-Spec B leakage test requirement.

As such, the record reflects that a person of ordinary skill in the art of urine containment bags would be informed with reasonable certainty that there is an outer leakage limit of 30 cubic centimeters of bodily fluid per 550 cubic centimeters of water over one minute of time based on the inverted leakage test outlined in the military specification Mil-Spec B. Nautilus, 134 S. Ct. at 2129; Wellman, Inc., 642 F.3d at 1367. Thus, the Court's construction of "prevent escape" to mean "substantially prevent escape" would not be indefinite to a person of ordinary skill in the art under 35 U.S.C. § 112, ¶ 2.

Conclusion

The Court construes the term "prevent escape" to mean "substantially prevent escape" in the context of the funnel means limitation in Claim 1 of the '139 Patent.

The parties shall file supplemental briefing clarifying their positions on invalidity and infringement in light of the Court's construction by **May 2, 2016**.

s/Mary Ellen Coster Williams
MARY ELLEN COSTER WILLIAMS
Judge